EXHIBIT 8

actavis
creating value in pharmaceuticals

May 21, 2008

RELEASE
REVIEWED: C.O. 3/13/09 DATE

Douglas I. Ellsworth
District Director
New Jersey District Office
United States Food and Drug Administration
10 Waterview Boulevard
Parsippany, NJ 07054

Re: Actavis Totowa

Dear Mr. Ellsworth:

In addition to the commitments Actavis made to FDA representatives in the wrap -up meeting for the inspection conducted at Actavis Totowa's Little Falls facility, as summarized in Robert Wessman's letter dated May 20, 2008, we submit this update as a brief summary of the actions taken by Actavis to address the concerns arising from the recent inspection of our Riverview Facility. Since our correspondence of May 6, 2008, Actavis Totowa and [redacted] (b)(4) have continued to pursue the actions and meet the commitments we outlined in that letter. We reaffirm our commitments regarding our Actavis Totowa facilities.

We will provide a more detailed analysis of each of the items discussed below in our responses to the FDA Form 483 observations. This letter is not intended to address inspectional observations, but rather to update FDA in respect to activities since our last report.

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On April 24, 2008, we stopped producing and shipping all products manufactured at Actavis Totowa. [redacted] (b)(4) subsequently reviewed records and data pertinent to batches of previously released product that were held in quarantine. These records included, among other things, (a) batch production documents, (b) in-process, finished product, and stability data relevant to the batch and product, (c) process validation data, (d) method validation data, and (e) equipment qualification reports. On the bases of its reviews, [redacted] (b)(4) either found that the reviewed batches met release requirements or did not meet such requirements. Actavis Totowa, on the strength of [redacted] (b)(4) findings, and its own evaluations, released a number of batches between May 1 and 15, 2008. **Attachment A**. Additional process validation work and investigations were initiated in respect to other batches that remain quarantined. Judgments about these batches, and if necessary previously distributed batches, will be made when investigations and validation projects have been completed. The company has not resumed manufacture of products intended for distribution. In addition, as committed during the meeting of May 20, Actavis will not release any of product manufactured prior to May 20 without first discussing such release with FDA.

All the recalls described in our April 9, 2008 letter have been initiated. Reports on these recalls are being prepared and our aim is to deliver them to the Agency on or before May 23, 2008. In addition to the foregoing recalls, we are in the process of initiating additional recalls (in certain cases, market withdrawals) of all Actavis Totowa prescription vitamins and other unapproved products. We decided to recall these products to the retail level. Our internal evaluation led us to conclude that it would be prudent to do so given the time it would take to

make further product assessments despite our strong commitment to put resources into such assessments. We shall process these recalls with all due haste and will provide FDA with updates and follow-up reports on them as soon as possible.

[redacted] (b)(4) currently is performing risk assessments for product batches within distribution to determine whether, for each product, there is an adequate basis for their distribution, or whether market intervention, by recall or withdrawal, is indicated. These reviews extend beyond the single batch records for particular lots, and take into account validations of processes and methods, stability data, qualification of equipment, OOS and deviation reports, and other relevant factors. A protocol has been developed and issued for this undertaking. We note that, to the extent that many of these factors were evaluated when [redacted] (b)(4) reviewed quarantined batches to determine their qualification for release, much of the underlying documentation for many products has been reviewed.

As we previously advised you, we decided to appoint new individuals to manage the operations and quality systems of Actavis Totowa. In addition to the appointment of Jeffery Rope as the Vice President of Operations at the Actavis Totowa site, to work in close association with Chris Young, the Director of US Solid Oral Dose Operations ("SOD"), we also have a new team of Directors and Managers to oversee the remediation efforts and day-to-day activities in Little Falls. Brian Nizio is now Director of Manufacturing, and [redacted] (b)(4) is Associate Director of Engineering & Maintenance. As previously stated to you, Phyllis Lambridis, Vice President of US Quality and Compliance now reports directly to me, and Tony Delicato was

appointed as Director of QA for SOD and has QA responsibility for both of our New Jersey sites. [redacted] (b)(6) Senior Manager of Quality Assurance from our Elizabeth, NJ site, has now assumed batch release responsibility for the Actavis Totowa site. [redacted] (b)(6) Senior Manager of the QA Investigations Group was hired to oversee the Investigation/Deviation, Complaints and CAPA processes at our SOD sites. The curricula vitae of these individuals are enclosed. **Attachment B**. They are charged with implementing immediate and long-term corrective actions to the manufacturing and quality systems at Actavis Totowa.

We have revised our SOPs for investigations and deviations and will conduct training on them prior to their implementation. The QA process will include a Material Review Board (MRB) to review product deviations. We also are developing a Quality Review Board (QRB) SOP. The QRB will review key quality indicators to evaluate performance of our Quality Systems. To assist the newly created investigations group in addressing the backlog of open investigations, we have hired the consulting group, [redacted] (b)(4).

We have developed a strategy for resuming manufacturing at the Actavis Totowa Little Falls plant. Our plan is to reintroduce production by adding one product at a time. We will not commence the distribution of any product until all open investigations with regard to that product are completed, and the [redacted] (b)(4) product risk assessment has been reviewed and determined to justify such action. A comprehensive protocol, currently in a draft form, will govern these activities. When finalized, a copy of such protocol will be provided to FDA.

In addition, we note that the following actions had been taken. We have:

a. improved the overall maintenance of the facility;

b. reviewed and rewritten certain SOPs and have trained all applicable facility personnel on them;

c. instituted a formal retraining on cGMPs for all facility personnel;

d. improved batch documentation based on feedback from [redacted] (b)(4), FDA and our own internal audits;

e. rebuilt all tablet presses and have ordered new presses, which are state of the art and include compaction force weight control and automation, for delivery within four to six weeks; and

f. implemented new SOPs for in-process sampling and product defect analysis in manufacturing.

As we have previously committed, [redacted] (b)(4) will also be undertaking a detailed audit of the site Quality Systems, and we will implement all of the corrective actions and enhancements deemed necessary as a result. In addition, when we recommence operations, it will be under the close supervision of the management team – and with the assistance of [redacted] (b)(4) consultant [redacted] (b)(4) until we are reasonably assured that our remediation efforts are firmly entrenched.

We will incorporate all of the above listed activities, as well as any others to address observations in the FDA Form 483, in a Corrective Action Plan. We shall provide this plan to the Agency shortly after the closeout of this inspection.

As noted in earlier correspondence, we stand ready to respond to any inquiry you may have. I may be reached at 908.764.5459.

Sincerely,

Sigurdur Oli Olafsson
Deputy, CEO Actavis Group &
CEO Actavis, Inc.

cc: Erin McCaffery
Andrew Ciaccia (HFR-CE 340)